REMARKS

Claims 1, 17-19 have been amended to recite that the claimed immediate release tablet is swallowable in view of the preparation of an immediate release suspension disclosed in Remon at page 24, line 23. Support for the amendments can be found throughout the specification at, for example, page 3, line 24 and page 5, line 24.

It is submitted that no new matter has been added by the above amendments.

Claims 1-20 are currently pending in the captioned application.

Anticipation Rejection

Claims 1-8, 10, and 17-20 were rejected under 35 USC §102(a) as anticipated by WO 01/21155 A1 ("Remon"). (Paper No. 20041025 at 2.)

For the reasons set forth below, the rejection, respectfully is traversed.

Remon discloses

(57) **Abstract:** Biologically inactive cushioning beads comprise at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least 30 % by weight of the biologically inactive cushioning beads. Such beads are useful for making solid shaped articles containing biologically active ingredients by compression.

The formulation of a solid oral dosage form, whether tablet or capsule, which disintegrates rapidly in water to form an instantaneous homogenous suspension of adequate viscosity to be swallowed could circumvent the problems of administering large dosages without premature release from controlled-release particles while providing a ready measured dose. The key to the development of such a dosage form is a rapidly disintegrating tablet which disperses to form a viscous suspension. A delay in the development of a viscous gel is essential for achieving disintegration of the tablet. On the

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properties.

The ideal solid oral dosage form should contain a swellable material which is able to increase viscosity on contact with water, at least one biologically active ingredient for immediate or sustained release delivery of the biologically active ingredient, and a filler conferring compactibility and the capability to disintegrate quickly. The inclusion of a viscosity increasing agent as a fine powder in the tablet matrix without any processing would interfere with disintegration and result in the formation of a voluminous hydrophilic mass which is impossible to disperse. Thus, it is necessary to incorporate such an agent into the tablet as granules or spheres so that the disintegration process occurs before the viscosity increase.

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The present invention may provide biologically inactive cushioning beads comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least about 30% by weight of the biologically inactive cushioning beads and which are useful for making solid shaped articles containing biologically active ingredients by compression.

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For the performance of the present invention, it is preferable to use a microcrystalline hydrocarbon wax having a congealing point between about 50°C and 90°C and which is water-insoluble. The microcrystalline hydrocarbon wax usually comprises a mixture of linear (normal) and branched (iso) hydrocarbons, According to a preferred embodiment of the present invention, the said mixture comprises from about 30 to about 90% by weight of linear hydrocarbons and from about 10 to about 70% by weight of branched hydrocarbons. Also preferably, the microcrystalline hydrocarbon wax

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flavoring agent (e.g. vanillin), buffering agent, filler, disintegrating agent and/or swellable material. Preferably the cushioning beads of the present invention include at least about 5% by weight of at least one such biologically inactive pharmaceutically acceptable additive (excipient) distributed throughout the beads, for instance in the form of an intimate mixture of wax and excipient. A disintegrating agent is especially useful as an excipient for providing quick-disintegrating characteristics when making a solid shaped article containing biologically active ingredients by compression.

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In making the rejection, the Examiner contended that

- "Remon teaches a rapidly disintegrating tablet comprising an active agent and wax particles." (Paper No. 20041025 at 2.)
- The wax is a microcrystalline wax or a natural wax. (*Id.*)
- The "composition further contains disintegrants, swellable materials as well as other fillers." (*Id.*)
- The wax particles have an average particle size of 0.5 to 2.0 mm. (*Id.*)
- The actives are chosen from a wide variety of known pharmaceutical agents. (*Id.*)
- The composition includes a film coating. (*Id.*)
- The tablets are produced by compression. (*Id.*)
- The tablets are rapid disintegration tablets. (*Id.*)

The Examiner admitted that "Remon does not refer to wax particles as powder." To fill the acknowledged gap, the Examiner looked to a dictionary definition for powder. Based on that definition the Examiner reasoned that since the claims of the captioned application "do not recite a particle size for the wax particles, the instant claims are deemed anticipated by Remon." (*Id.*)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

Initially, we note that there must be no difference between what is claimed and what is disclosed in the applied reference. "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads.

The rejection failed to identify where in Remon each and every element of claims 1-8, 10, and 17-20 are shown. In particular, the Examiner failed to identify where in Remon there is a specific disclosure of the required immediate release tablet having, among other things, at least 60 weight percent of an active ingredient or an immediate release tablet that is swallowable.

Because the Examiner has not met the requisite burden, the rejection is improper and should be withdrawn.

Obviousness Rejection

Claims 9 and 16 were rejected under 35 USC §103(a) as being unpatentable over Remon. (Paper No. 20041025 at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Remon's disclosure set forth above is incorporated herein by reference.

In making the rejection, the Examiner incorporated the assertions set forth in the anticipation rejection above into the instant rejection. The Examiner acknowledged, however, that Remon "does not expressly teach the same concentration of wax or active agent or the same particle size for the wax particles." (Paper No. 20041025 at 3.)

To fill the acknowledged gap, the Examiner relied upon the assumption that such "limitations would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results." (*Id.*) The Examiner opined that "the results must be those that accrue from the specific limitations."

The Examiner then concluded that, "one of ordinary skill in the [art] would have been motivate "to prepare similar tablets with different active agents that achieve the same goal of rapid disintegration." (*Id.*) The Examiner then asserted that "the type of active agent incorporated into the composition determines the concentration of the active agent and may also vary the amount of other components.

For a *prima facie* case of obviousness to be established, the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art. The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

It is not seen where there is any suggestion or motivation based on Remon to make, among other things, a swallowable immediate release tablet. Remon at p. 24, line 23, discloses using a solid agent for preparing an immediate release suspension. It is not seen where the disclosure of an immediate release suspension would provide the requisite motivation. For this reason, the rejection is improper and should be withdrawn.

In addition, it is not seen where Remon provides the requisite motivation to one of ordinary skill in the art for the required immediate release tablet having, among other things, at least 60 weight percent of an active ingredient. The Examiner opined that "the type of active agent incorporated into the composition determines the concentration of

active agent." However, the Examiner failed to provide any suggestion or motivation for the specifically claimed invention. For this additional reason, the rejection is improper and should be withdrawn.

Claims 11-15 were rejected under 35 USC §103(a) as being unpatentable over Remon in combination with US Pat. No. 5,494,681 ("Cuca"). (Paper No. 20041025 at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Remon's disclosure set forth above is incorporated herein by reference.

Cuca discloses a tastemasked system by casting or spin congealing melt dispersions and/or solutions of drug or other active material, or combinations of drugs or medicaments in a molten blend of materials. (Col. 2, lns. 64-67.) Cuca further discloses that a substantially tasteless pharmaceutical delivery system is formed which comprises: (a) an active material or a combination of drugs or medicaments; and (b) a spatially oriented matrix comprising (i) a major amount of wax core material having a melting point within the range of about 50°C. and about 200°C.; and (ii) a minor amount of a hydrophobic polymer material. (Col. 3, lns. 1-6 and 56.)

In making the rejection, the Examiner incorporated the assertions set forth above in the anticipation rejection into the instant rejection. The Examiner acknowledged, however, that Remon "does not expressly teach including a second active agent." (Paper No. 20040220 at 4.)

To fill the acknowledged gap, the Examiner looked to Cuca as "teach[ing] that tablet formulations can comprise one or more active agents."

The Examiner reasoned that one of ordinary skill in the art would have been motivated to use more than one active agent "to provide a composition that better delivers a therapeutic dose to the host to better combat the disease or condition being treated." (*Id.*) The Examiner then concluded that "at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a tablet formulation with one or more active agents incorporated into the composition. (*Id.*)

For a *prima facie* case of obviousness to be established, the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art. The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

It is not seen where there is any suggestion or motivation based on Remon to make, among other things, a swallowable immediate release tablet. Remon at p. 24, line 23, discloses using a solid agent for preparing an immediate release suspension. It is not seen where the disclosure of an immediate release suspension would provide the requisite motivation. It is not seen in this record where Cuca closes that gap. For this reason, the rejection is improper and should be withdrawn.

In addition, it is not seen where Remon provides the requisite motivation to one of ordinary skill in the art for the required immediate release tablet having, among other things, at least 60 weight percent of an active ingredient. The Examiner opined that "the type of active agent incorporated into the composition determines the concentration of active agent." However, the Examiner failed to provide any suggestion or motivation for the specifically claimed invention. Nor is it seen in this record where Cuca closes that gap. For this additional reason, the rejection is improper and should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP §707.07(j) or in making constructive suggestions pursuant to MPEP §706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

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DATE: December 20, 2004